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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/842,466

04/26/2001

Hiroyasu Kokubo

35576/233803

8005

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7590

07/28/2005

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EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/842,466

Applicant(s)

KOKUBO ET AL.

Examiner

Humera N. Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-9, 11, 13-20 and 31-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-9, 11, 13-20 and 31-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

5.00

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 C.F.R. §1.114 filed 06/03/05, Applicant's Amendment and Arguments/Remarks, both filed 05/02/05 is acknowledged.

Claims 6-9, 11, 13-20 and 31-47 are pending. Claims 31 and 33 have been amended. Claims 1-5, 10, 12 and 21-30 have previously been cancelled. Claims 6-9, 11, 13-20 and 31-47 are rejected.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/03/05 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6-9, 11, 13-17 and 31-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hampton *et al.* (US Pat. No. 5,089,270).

The instant invention is drawn to a solid preparation coated with a multi-colored continuous film coating layer, prepared by the process of coating a solid preparation with a continuous film coating layer having one or more colorants; and exposing a first part of the coating layer to a first amount of radiation and exposing a second part of the coating layer to a second amount of radiation under conditions sufficient to result in the first and second parts of the coating layer having different coloration.

Hampton *et al.* ('270) teach a multi-characteristic, bi-layered, two-color, capsule-shaped tablet consisting of a first and second different coloring agent and a blend of one or more excipients and active substances. The multi-colored tablet is coated with a clear coating, such as gelatin, to provide a solid medicament with the appearance of a gelatin capsule (see Abstract).

The multiple characteristic tablet comprises different color sections, which includes a color demarcation line (22) extending transversely between the halves (14 & 18) of the core. The

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core (12) is preferably coated with a clear material (24). The coloring agents employed are conventional and any desired color combination could be employed (col. 3, lines 5-38).

A feature of the invention is to coat the bi-layer, two-colored tablet with a single coating of gelatin or a film-forming polymeric substance, which will simulate the appearance, and function of the gelatin capsule. Suitable film-forming materials include methylcellulose, hydroxypropyl methylcellulose, polyvinylpyrrolidone, ethylcellulose, various derivatives of methacrylic acids and methacrylic acid esters, and cellulose acetate phthalate (col. 5, lines 37-49). The coating of the film-forming polymer may be applied in several ways, such as by using conventional coating pans. Spray guns or other suitable atomizing equipment may be introduced into the coating pans to provide spray patterns conducive to rapid and uniform coverage of the tablet bed. The coating material is sprayed until the tablets are uniformly coated to the desired thickness and desired appearance of the tablet (col. 5, line 59 – col. 6, line 15).

The examples at columns 7-9 demonstrate two-colored, bi-layered capsule-shaped tablets. For instance, Example 1 demonstrates a bi-layered capsule-shaped tablet made from two separate layers, which were compressed together on a tablet press to form a tablet with an appearance similar to a capsule's appearance.

The instant claims are drawn to a solid preparation coated with a multi-colored continuous film coating layer prepared by coating a solid preparation with a continuous film-coating layer having one or more colorants; and exposing a first part of the coating layer to a first amount of radiation and exposing a second part of the coating layer to a second amount of radiation under conditions sufficient to result in the first and second parts of the coating layer having different coloration.

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A product is being claimed in which the solid preparation comprises more than one distinct coloring agent. It is the position of the Examiner that the prior art expressly teaches a two-colored, bi-layered tablet formulation consisting of a first and second different coloring agent, wherein the tablet is provided with a single continuous coating layer and film-forming agents. The instant claims are product claims and it is the patentability of the product that must be established, *per se*. Applicants have not demonstrated any unexpected or surprising results that accrue from the multi-colored, continuous film coating layer as claimed. The prior art recognizes and teaches a tablet that is multi-colored and has two layers that provide for distinct colors with different color sections, provided for easy recognition of the tablet. The prior art formulations provide for tablets having multi-colored arrangements, albeit in the body of the tablet. Additionally, no unexpected results are observed in the instant process of forming the distinct coloration solid preparation, since the end result is a solid product having one or more different colors. The prior art explicitly teaches a tablet formulation having more than one distinct color on the tablet.

Thus, it would have been deemed *prima facie* obvious to one of ordinary skill in the art, given the teachings of Hampton *et al.*, to formulate a two-colored, bi-layered tablet formulation consisting of first and second distinct coloring agents, wherein the tablet is provided with a single continuous coating layer and film-forming agents, with the expected result of obtaining a multi-colored tablet, that allows for easy recognition of the tablet.

Claims 18-20 and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hampton *et al.* (US Pat. No. 5,089,270) as applied to claims 6-9, 11, 13-17 and 31-44 above, and further in view of Hoover *et al.* (US Pat. No. 5,464,631).

Hampton *et al.* ('270), as discussed above, teach a multi-characteristic, bi-layered, two-color, capsule-shaped tablet consisting of a first and second different coloring agent and a blend of one or more excipients and active substances. The multi-colored tablet is coated with a clear coating, such as gelatin, to provide a solid medicament with the appearance of a gelatin capsule (see Abstract).

Hampton *et al.* teach color demarcation lines on the tablet. Hampton *et al.* do not teach the inclusion of patterns comprising logos, bar codes or letters.

Hoover *et al.* ('631) teach a two-colored medicament dosage form having embossed or debossed letters, logos, symbols and the like on the surface of the dosage form (see reference column 4, lines 37-44).

It would have been obvious to use the combined teachings of Hoover *et al.*, who teaches a two-colored medicament comprising embossed letters, logos, symbols and the like, within the formulation of Hampton *et al.* who teaches a two-colored tablet with distinct color demarcations because Hoover *et al.* teach that the embossed letters, logos and symbols provide for visual perception, brand name recognition and an aesthetic appearance of the dosage form. The expected result would be a distinct, visually improved solid dosage form for easier brand recognition.

Response to Arguments

Applicant's arguments filed 05/02/05 have been fully considered but they are not persuasive.

Applicant argued in regards to the 35 U.S.C. §103(a) rejection of claims 6-9, 11, 13-17 and 31-44 over Hampton et al. (US 5,089,270) and the 35 U.S.C. §103(a) rejection of claims 18-20 and 45-47 over Hampton ('270) in view of Hoover (US 5,464,631) stating, "Hampton does not disclose or suggest the multi-colored continuous film coating layer of the invented preparation. In fact, Hampton's specific description of a clear coating layer teaches away from the recited multi-colored continuous coating layer. Hoover provides no disclosure or suggestion of a multi-colored continuous film layer. The disclosure of Hoover fails to cure the deficiencies of Hampton, and even the combination of the references fails to teach or suggest the multi-colored continuous film layer."

Applicant's arguments have been thoroughly considered, but were not found to be persuasive. No unexpected or surprising results accrue from the multi-colored continuous film coating layer, since the prior art recognizes and teaches multi-colored tablets having two layers that provide for distinct colors with different color sections, provided for easy recognition of the tablet. The prior art formulations provide for tablets having multi-colored arrangements, albeit in the body of the tablet. Applicant's argument that 'the disclosure of Hoover fails to cure the deficiencies of Hampton and that Hoover provides no disclosure or suggestion of the recited multi-colored continuous film layer' is not persuasive since Applicant's have not demonstrated any unusual or unexpected results that accrue from the instant film coating layer recited. The

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prior art formulations nevertheless, teach tablets having multi-colored arrangements. Hoover et al. was cited for their teaching that it is known in the art to employ patterns that include logos, bar codes or letters in multi-colored tablet formulations. According to Hoover, the embossed letters, logos and symbols provide for visual perception, brand name recognition and an aesthetic appearance of the dosage form (see Hoover col. 4, lines 37-43). It is the position of the Examiner that the presence of logos in a solid preparation would provide for different color intensities on the surface of the preparation and thus would also meet Applicant's desired properties. The prior art recognizes tablet formulations having more than one distinct color on the tablet. Thus, the instant invention is rendered *prima facie* obvious over the cited art of record.

Applicant further argued, "The Office has declined to give weight to the coating layer distinction on the basis that the distinction was recited in the process steps of product-by-process claims. However, the claimed solid preparation is recited as the product prepared by the steps of coating the solid preparation with a continuous film coating layer, and exposing the coating layer to radiation sufficient to result in first and second parts of the coating layer having different coloration. Thus, the resulting product necessarily has a continuous film coating layer having parts with different coloration. The coating layer is a structural element of the claimed preparation, which should not be disregarded on the basis that the preparation is claimed in product-by-process format. The claims now specifically and structurally recite that the coating layer distinguishes the claimed preparation from the tablets of the references."

Applicant's arguments have been thoroughly considered, but were not found to be persuasive. There are no unusual or unexpected results attributable to the radiation steps claimed

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by Applicants, since the radiation steps do not impart any additional properties to the product being claimed. Moreover, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In the instant case, the tablet of Hampton et al. is a multi-colored product having two layers wherein distinct colors with different color sections are provided for easy recognition of the tablet. The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). Burden is shifted to Applicant to establish that the multi-colored continuous coating layer, as now claimed provides improved results over the prior art tablet formulations. The prior art teaches and suggests two-colored or multi-colored tablets that offer more than just one distinct color, albeit in the body of the tablet.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh 

Patent Examiner

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July 22, 2005